



COMMISSION STAFF WORKING DOCUMENT¹

Basic Substance
Hydrogen peroxide
SANTE/11900/2016– rev. 1
24 January 2017

Final Review report for the basic substance hydrogen peroxide
Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on
24 January 2017
in view of the approval of hydrogen peroxide as basic substance in accordance with Regulation
(EC) No 1107/2009

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of hydrogen peroxide made in the context of the assessment of the substance provided for in Article 23 of Regulation (EC) No 1107/2009² concerning the placing of plant protection products on the market, with a view to the possible approval of this substance as basic substance.

In accordance with the provisions of Article 23(3) of Regulation (EC) No 1107/2009, the Commission received on 9 December 2015 an application from Institut Technique de l'Agriculture Biologique (ITAB), hereafter referred to as the applicant, for the approval of the substance hydrogen peroxide as basic substance.

The application and attached information were distributed to the Member States and European Food Safety Authority (EFSA) for comments. The applicant was also allowed to address collated comments and provide further information to complete the application, which was finalised in the new version of July 2016.

In accordance with the provisions of Article 23(4) of Regulation (EC) No 1107/2009 the Commission required scientific assistance on the evaluation of the application to EFSA, who delivered its views on the specific points raised in the commenting phase.

EFSA submitted to the Commission the results of its work in the form of a technical report for hydrogen peroxide on 13 September 2016³.

The Commission examined the application, the comments by Member States and EFSA and the EFSA Technical report on the substance together with the additional information and comments

¹ Does not necessarily represent the views of the Commission.

² OJ L 309, 24.11.2009, p. 1-50.

³ European Food Safety Authority, 2016; Outcome of the consultation with Member States and EFSA on the basic substance application for hydrogen peroxide for use in plant protection as fungicide and bactericide in seed treatment and for disinfecting cutting tools. EFSA supporting publication 2016:EN-1091. 39 pp.

provided on it by the applicant, before finalising the current draft review report, which was referred to the Standing Committee on Plants, Animals, Food and Feed for examination. The draft review report was finalised in the meeting of the Standing Committee of 24 January 2017.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the EFSA technical report, and the comments and clarifications submitted (background document C), all these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed in support of the **Commission Implementing Regulation (EU) 2017/409⁴** concerning the approval of hydrogen peroxide as basic substance under Regulation (EC) No 1107/2009.

The review report will be made available for public consultation by any interested parties.

Without prejudice to the provisions of Regulation (EC) No 178/2002⁵, in particular with respect to the responsibility of operators, following the approval of hydrogen peroxide as basic substance, operators are responsible for using it for plant protection purposes in conformity with the legal provisions of Regulation (EC) No 1107/2009 and with the conditions established in the sections 4, 5 and Appendixes I and II of this review report.

EFSA will make available to the public all background documents and the final Technical Report of EFSA, as well as the application without the Appendixes and excluding any information for which confidential treatment is justified in accordance with the provisions of Article 63 of Regulation (EC) No 1107/2009.

Products containing exclusively one or more basic substances do not require authorisation in line with derogation set under Article 28 of Regulation (EC) No 1107/2009. As a consequence, no further assessment will be carried out on such products. However, the Commission may review the approval of a basic substance at any time in conformity with the provisions of Article 23(6) of Regulation (EC) No 1107/2009.

3. Overall conclusion in the context of Regulation (EC) No 1107/2009

The overall conclusion based on the application, including the results of the evaluation carried out with the scientific assistance of EFSA, is that there are clear indications that it may be expected that hydrogen peroxide fulfils the criteria of Article 23.

⁴ OJ L 63, 9.3.2017, p. 95–97.

⁵ OJ L 31, 1.2.2002 p. 1-24 - Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

Hydrogen peroxide does not fulfil the criteria of a ‘foodstuff’ as defined in Article 2 of Regulation (EC) No 178/2002.

Considering the EFSA conclusions on the basic substance application for hydrogen peroxide, the rate of application and the conditions of use which are described in detail in Appendix I and II, it is concluded that the use of hydrogen peroxide would not lead to concerns for human health. Furthermore, the conditions of use are not expected to lead to the presence of residues of concern in food or feed commodities.

Hydrogen peroxide does not have an inherent capacity to cause endocrine disrupting (according to the interim criteria in Regulation (EC) No 1107/2009), neurotoxic or immunotoxic effects and is not predominantly used for plant protection purposes but nevertheless is useful in plant protection in a product consisting of the substance and water. Finally, it is not placed on the market as a plant protection product.

It can be concluded that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment when used in accordance with the supported uses as described in Appendix II.

In fact, these indications were reached within the framework of the uses which were supported by the applicant and mentioned in the list of uses supported by available data (attached as Appendix II to this review report) and therefore, they are also subject to compliance with the particular conditions and restrictions in sections 4 and 5 of this report.

Extension of the use pattern beyond those described above will require an evaluation at Community level in order to establish whether the proposed extensions of use can still satisfy the requirements of Article 23 of Regulation (EC) No 1107/2009.

The following points were considered as open by EFSA (2016) for hydrogen peroxide, reasons follow to explain why the risk is considered negligible:

Chapter 5 – Impact on human and animal health

- *With regards to the impact on human and animal health, a number of potential adverse effects are reported mainly after oral ingestion that would require a dose-response characterisation to perform a proper risk assessment relevant to operators, workers, bystanders and to residential exposure. Therefore the information provided is insufficient to conclude on the non-dietary exposure risk assessment.*

Since the ready-made hydrogen peroxide solutions are used for disinfection of agricultural cutting tools and for seed treatment and not sprayed, exposure by operators, workers, bystanders and residents via the oral route can be assumed to be negligible. Moreover, the risk of the biocidal use of hydrogen peroxide solutions (<5%) as a hand disinfectant in hospital and food industry use was considered to be acceptable by the Biocidal Products Committee of the European Chemicals Agency⁶.

⁶ European Chemical Agency, Biocidal Products Committee (BPC): Opinion on the application for approval of the active substance: Hydrogen peroxide, Product type: 1, ECHA/BPC/39/2015

- *Regarding skin, eye, respiratory tract irritation and/or corrosivity and repeated inhalation toxicity, low concern would be assumed at concentrations below 5% due to a low irritation potential; however 5%, the highest concentration proposed to be used for disinfection of mechanical cutting tools, require classification as Eye Irrit. 2, H319: Causes serious eye irritation.*

As noted in the EFSA technical report, solutions of hydrogen peroxide below 5% are not classified as Eye Irrit. 2. The intended use of the basic substance considers only solutions with a concentration lower than 5%, as described in the table of intended uses in Appendix II.

4. Identity and biological properties

The main properties of hydrogen peroxide are given in Appendix I.

The active substance is to be used in a ready-made solution with a concentration below 5%. The hydrogen peroxide used for the manufacture of the solution shall have a purity according to the FAO JECFA specifications.

It has been established that for hydrogen peroxide as notified by the applicant, no relevant impurities are considered, on the basis of information currently available, of toxicological, ecotoxicological or environmental concern.

5. Particular conditions to be taken into account in relation to the uses as basic substance of hydrogen peroxide

Hydrogen peroxide must be identified by the specifications given in Appendix I and must be used in compliance with conditions of supported uses as reported in Appendixes I and II.

The following conditions for use deriving from assessment of the application have to be respected by users:

- Only uses as basic substance being a fungicide and bactericide in seed treatment and for disinfecting agricultural cutting tools are approved.

Use of hydrogen peroxide must be in compliance with conditions specified in the Appendixes I and II of this review report.

On the basis of the proposed and supported uses (as listed in Appendix II), no particular issues have been identified.

6. List of studies to be generated

No further studies were identified which were at this stage considered necessary.

7. Updating of this review report

The information in this report may require to be updated from time to time to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 23 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, as appropriate, in connection with any amendment of the approval conditions for hydrogen peroxide in Part C of Annex of the Regulation (EC) No 540/2011.

8. Recommended disclosure of this review report

Considering the importance of the respect of the approved conditions of use and the fact that a basic substance will be not placed on the market as plant protection product, hence, no further assessment will have to be carried out on it, it is very important to inform not only applicants but also potential users on the existence of this review report.

It is therefore recommended that the competent authorities of Member States will make available such report to the general public and operators by means of their national relevant websites and by any other appropriate form of communication to ensure that the information reaches potential users.

APPENDIX I

Identity and biological properties

HYDROGEN PEROXIDE

Common name	Hydrogen peroxide
Chemical name (IUPAC)	Hydrogen peroxide
Chemical Name. (CA)	Hydrogen peroxide
CAS No	7722-84-1
CIPAC No and EEC No	Not applicable
FAO SPECIFICATION	Not applicable
Purity	Solution in water (<5 %) The hydrogen peroxide used to manufacture the solution shall have a purity according to the FAO JECFA specifications.
Molecular formula	H ₂ O ₂
Relevant impurities	Not applicable.
Molecular mass and structural formula	H ₂ O ₂ Molecular mass: 34.01 g mol ⁻¹
Mode of Use	Hydrogen peroxide as specified above to be used as water solution for application as listed in Appendix II.
Preparation to be used	Hydrogen peroxide ready-made solution of <5% concentration.
Function of plant protection	Fungicide, bactericide.

APPENDIX II

List of uses supported by available data HYDROGEN PEROXIDE

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks
					Type (d-f)	Conc Of a.i. g/L (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	kg a.i./hl min max (g/hl)	Water l/ha min max	kg a.i./ha min max (g/ha) (l)	kg a.i./ha min max (g/ha) (l)		
Vegetables Solanaceae spp like Tomato <i>Lycopersicon esculentum</i> bell pepper Capsicum spp	EU	Generic ready-made <5% hydrogen peroxide solution	G	Soil bacteria <i>Ralstonia Solanacerum Botrytis Botrytis cinerea</i>	Liquid for disinfection of agricultural mechanical cutting tools Concerned Tools Small Miscellaneous equipment: Cuttings scissor with injection (LS) *	15 to 30	Apply before cutting	n.a.	To be applied before every use of the tool	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	Waiting period 30 seconds after washing

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks (*,**) (n)
					Type (d-f)	Conc of a.i. g/L (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	kg a.i./hl min max (g/hl)	Water l/ha min max	kg a.i./ha min max (g/ha) (l)			
Lettuce <i>Lactuca sativa</i>	EU	Generic ready-made <5% hydrogen peroxide solution	F G	Bacterial leaf spot pathogen <i>Xanthomonas campestris</i> pv. <i>vitians</i>	Liquid for Seed Treatment (LS) *	10 to 15	Seed treatment before sowing**	n.a.	1	None	n.a.	n.a.	n.a.	Seeds are temporary deep in the preparation then removed	n.a.	Seeds are immersed in the prepared solution for 5 to 15 min (Seed Treatment)
Horticulture flowers Like common zinnia <i>Zinnia elegans</i>				Fungi, especially pathogenic <i>Alternaria zinnia</i> <i>Alternaria alternata</i> <i>Fusarium</i> Spp.		25 to 49										

* Preparation by using or diluting a ready-made solution of hydrogen peroxide (<5%).

** Treatment, just before sowing.

(a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)

(c) e.g. pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor

(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..

(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO)

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) Indicate the minimum and maximum number of application possible under practical conditions of use

(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)

(m) PHI - minimum pre-harvest interval